APPENDIX E

APPLICATION OF CONNELL ET AL

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1. Description of storing and retrieving patient data to and from a RAM card.

Transportation of data to and from the System 1000 machine will be possible through the use of a memory card (in addition to serial port communication).

The information stored and retrieved from the card include:

1. Logging of treatment data to be later recalled for therapy analysis:
   - -A, B, and Primary Temperatures
   - -A, B, and Primary Conductivities
   - -Veneous, Arterial, Dialysate, Systolic, and Diastolic Pressures
   - -Blood flow rate, total blood processed
   - -UF rate, total UF removed, UF goal
   - -Machine state

2. Treatment prescription to be read by the machine for possible programmable Na, UF, Bicarb profile uploading.
   - -UF rate profile over time
   - -Na concentration profile over time
   - -Bicarb concentration profile over time
   - -Blood Pump flow rate
   - -Treatment time
   - -Goal UF removal volume
   - -Dialysate flowrate
   - -Dialysate temperature
   - -Blood pressure measurement schedule and alarms
   - -Heparin prescription

3. Unique codes stored on the card when read by the System 1000 machine will initiate special modes (calibration mode, technician mode, enable the blood pressure monitor function, modification of the parameters transmitted over the serial port for diagnostics,...)

1. Logging of treatment data to be later recalled for therapy analysis

Using a program written to interface with a memory card read r/writer that is run on an external personal computer, a person is able to program/format System 1000 memory cards. These formatted cards when connected to the system 1000 will identify what treatment parameters are to be stored in the card and how often. During a treatment the desired data will be stored on the card periodically as defined by the sample period formatted on the card. In this way, either the amount of data per treatment or the number of treatments per card can be maximized. This type of data logging enables physicians to characterize a patient's response to treatment variations. After identifying the interrelated treatment factors, the physician on subsequent treatments can limit the data stored to the card and possibly increase the sample rate. In this way, the maximum sample of the most important treatment parameters are saved.

If treatment characterization is not the goal an operator has the option of retrieving just the final treatment parameters for a treatment overview type of record.

To retrieve the data from the card the physician will use a memory card reader connected to a personal computer. A program will read the card and store its data in a file that can be read by most spreadsheets. The program will allow the physician to choose which treatment record is to be read from the card (by name and/or date indication).

Althin Drake Willock will also provide a kenetic modeling program which will analyze the data stored to the card. The modeling program will be used to generate the goal parameters for the next dialysis treatment (and is explained below).

2. Treatment prescription to be read by the machine for possible programmable Na, UF, Bicarb profile downloading.

Using a program written to interface with a memory card reader/writer that is run on an external personal computer, a person is able to program/format System 1000 memory cards. When these programmed cards are read by the System 1000, upon user command, various settings will be stored in the machine. The System 1000 machine will then require the operator to verify that each of the stored parameters is to be used by the machine. If no verification is made, machine operation is unchanged.

By programming a card for specific treatment parameters (blood and dialysate flow rates, dialysate temperature, UF removal goal, treatment time, and ...) and then instructing a nurse to use the machine settings on the card, a physician can gain more control of the dialysis session.

Programmable treatments can be set up on a personal computer using the kinetic modeling program written by Althin Drake Willock. This program will use past treatment data and daily conditions to generate and store Na concentration, UF rate and bicarb concentration profiles in the card (blood flow rate and other parameters are also calculated).

The physician will always be able to modify any of the program generated information (treatment profiles and settings) to better suit his knowledge and experimentation in the field.

3. Unique codes stored on the card when read by the System 1000 machine will initiate special modes (calibration mode, technician mode, enable the blood pressure monitor function, modification of the parameters transmitted over the serial port for diagnostics,...)

Certain modes of the System 1000 machine require special switch settings inside the machine for initiation. This is a good way of avoiding accidental mode initiation, yet the use of the memory card for this purpose is more convenient and just as secure. The memory card allows the user to change to technician mode without turning the machine off or opening the machine up. The calibration mode will still require the machine to be turned off before it can be entered, yet the opening of the machine can be avoided.

When used with a serial port monitor the memory card can request various types and amounts of information to be transferred over the serial port for remote machine diagnosis. If no serial monitor is available the information can be stored in the memory card so that the technician can be evaluate the information later, with the use of a card reading program.

The programming of the cards to perform the above described functions will be done by running an Althin Drake Willock program on a computer with a memory card reader/writer.

2. List of all System 1000 tech messages.

All of the quoted strings below are technician level warning messages.

The system name above message groups is for reference only.

References to items with parenthesis, like bp_input(), indicate software functions. Failures of functions, like an illegal index, should never occur yet when the code was written these messages aided the debugging process.

* The extremely useful technician messages are denoted with a "*" (these messages typically aid in the troubleshooting of mechanical malfunctions).

```
BLOOD PUMP SYSTEM
"illegal qlen in BP_XMIT"
"Blood Pump Low Speed"                    *
"BP Control Shutdown"                     *
"BP Command Error"                        *
"Blood Pump Overspeed Alarm"              *
"Bld Pmp Overspeed Alarm"                 *
"Illegal index in bp_xmit()"
"Illegal index in bp_input()"
"long timer error"

UF/PROP SYSTEM
"Too much time between EOS signals"       *
"Early EOS detection"                     *
"UF SHUTDOWN"                             *
"UF Command Error"                        *
"UF Time scheduled Event Error"           *
"Unidentified Error in MISC_ERRFLG"
"A Pump Noise"                            *
"A Pump Missed Steps"                     *
"B Pump Noise"                            *
"B Pump Missed Steps"                     * (for three pump system)
"C Pump Noise"                            *
"C Pump Missed Steps"                     *
"A temperature probe error"               *
"B temperature probe error"               *

IO SYSTEM
"illegal qlen in IO_XMIT"
"IO_XMIT: bad stat chnge %d,%d"
 "Illegal io_xmit() index"
"Illegal index in io_input()"
"Illegal index in ioport_xmit()"
```

```
IOPORT SYSTEM                                          *
"No 8255... port terminated"                           *
"Set_pwr_state: hw_ver=1"
"Set_pwr_state: hw_ver=2"
"Set_power_state: Can't power on"                      *
"Set_power_state: Can't power off"                     *
"Converse: illegal return from uccom()"
"Switch failure in reset_port() function"
"Command buffer full in add_cmd()"
"Unrecognizable command in make_cmd()"
"Illegal number of data bytes in make_cmd()"
"Illegal number of data bytes in make_cmd()"
```

3. List of all routinely saved and retrieved machine states and settings.

All parameters below are saved every 30 seconds or upon any major machine state change. When the System 1000 machine is turned on, if the current time is less than 20 minutes later than the time stamp data (last time data was saved) all the below parameters are restored.

temperature correction

accumulated uf volume removed
desired UF removal volume
UF removal rate
UF Override flag

current machine state
previous machine state
selftest pass/fail flag

time stamp
prescribed dialysis time
elapsed treatment time

prescribed or elapsed treatment time display flag
manual or calculated uf rate display flag

heparin pump rate

accumulated blood
accumulated heparin

window limits for
conductivity, temperature, prescribed time, heparin ...

4. Cobe, Fresenius, and Drake Bicarb Proportioning Ratios

Bicarbonate Proportioning Ratios	(Dialysate:Bicarb:Acid)
1. Cobe Concentrates	45 :1.43 :1
2. Fresenius Concentrates	35 :1.225:1
3. Drake Concentrates	36.83:1.83 :1
Acetate Proportioning Ratio	35 :0 :1

System 1000 Bicarbonate Proportioning Ratios, M Hogard, 4/15/91

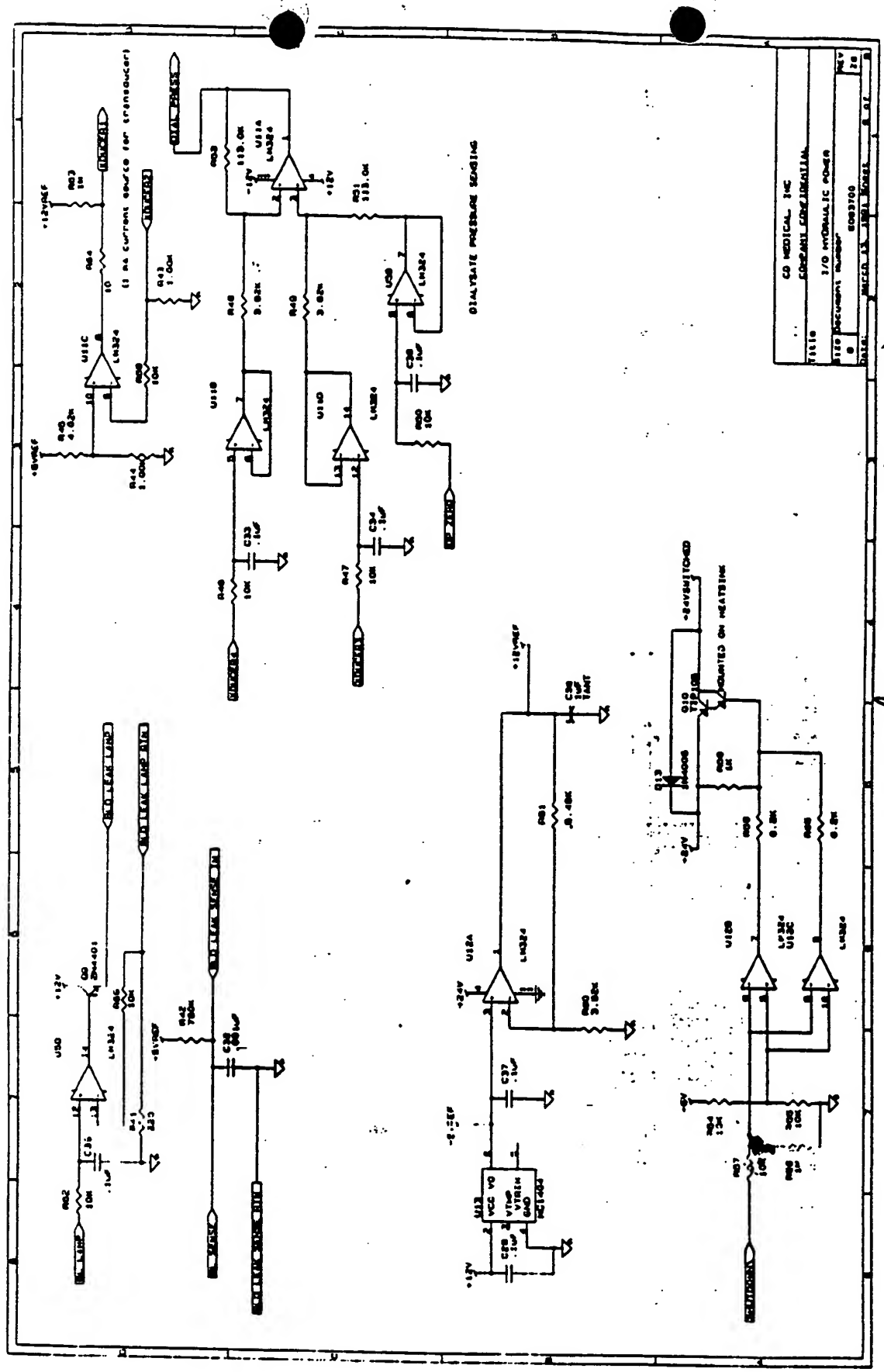
5. Schematics of the following circuitry:
   a. blood leak detector
      IO Hydraulic Power Board Page 8 of 8 REVZ6

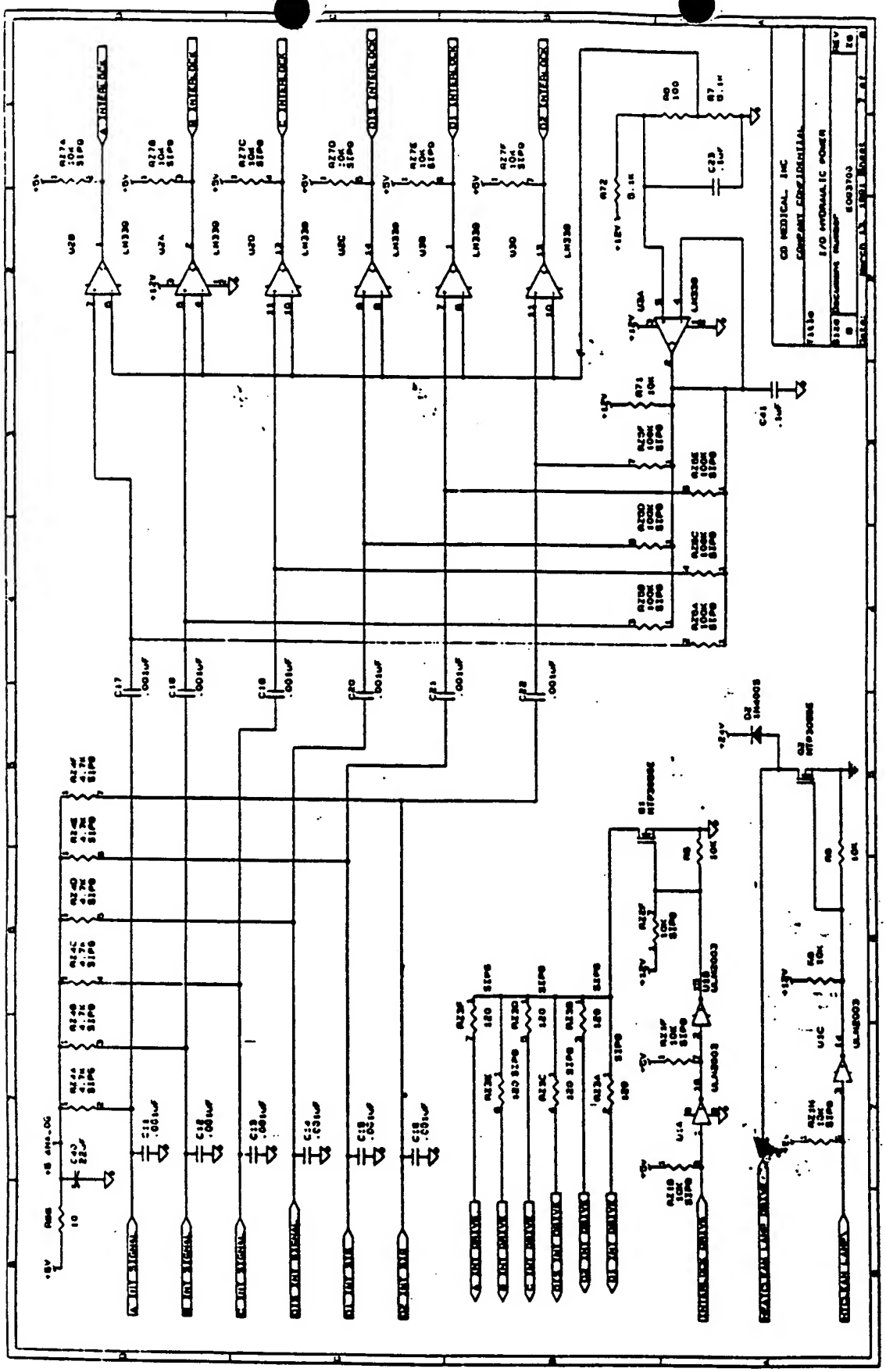
   b. interlock detectors
      IO Hydraulic Power Board Page 7 of 9 REVZ6

   c. air detector
      IO Electric Power Board Page 3 of 3 REVZ9

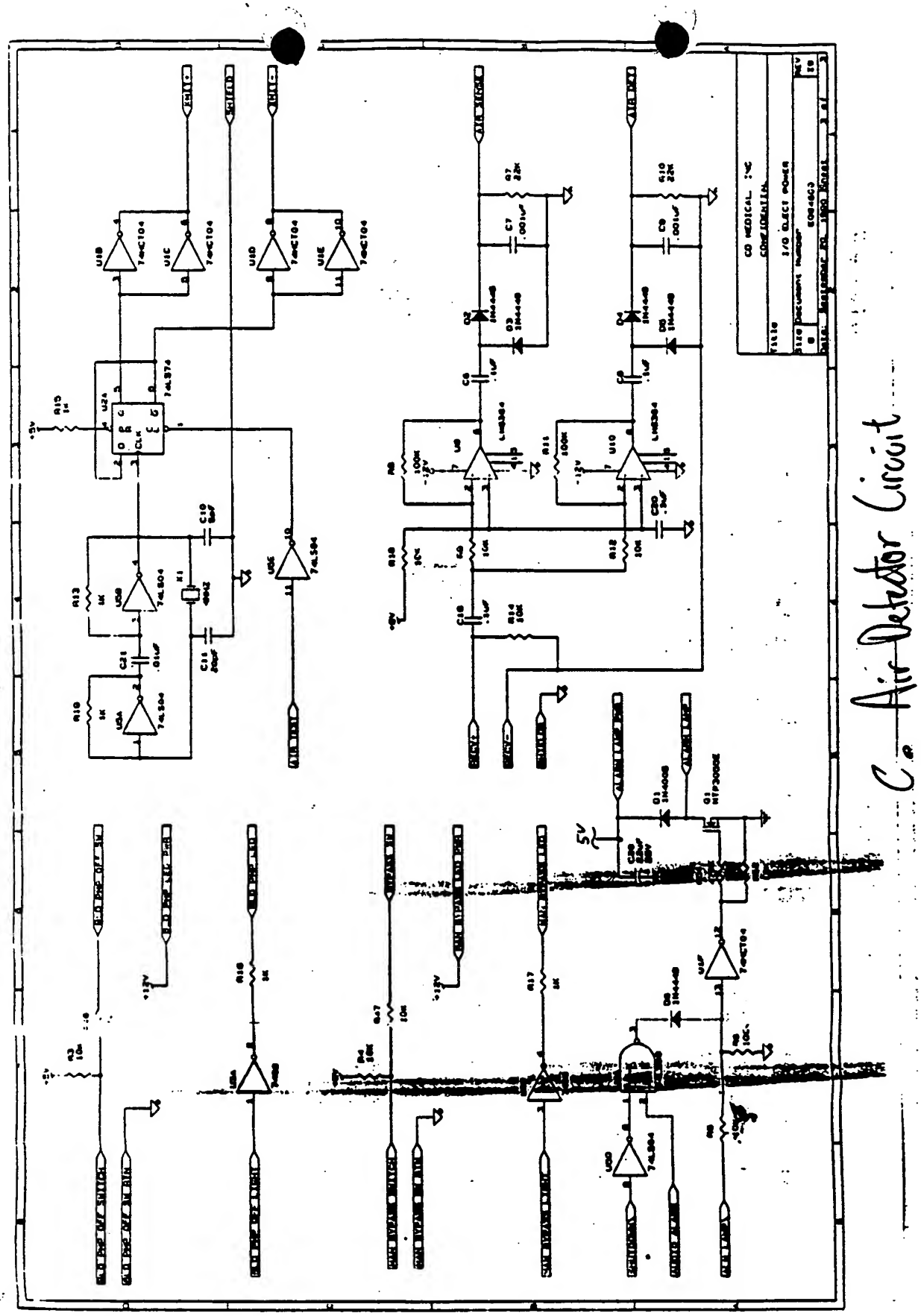
   d. conductivity and temperature monitors
      IO Hydraulic Power Board Page 5 of 8 REVZ6

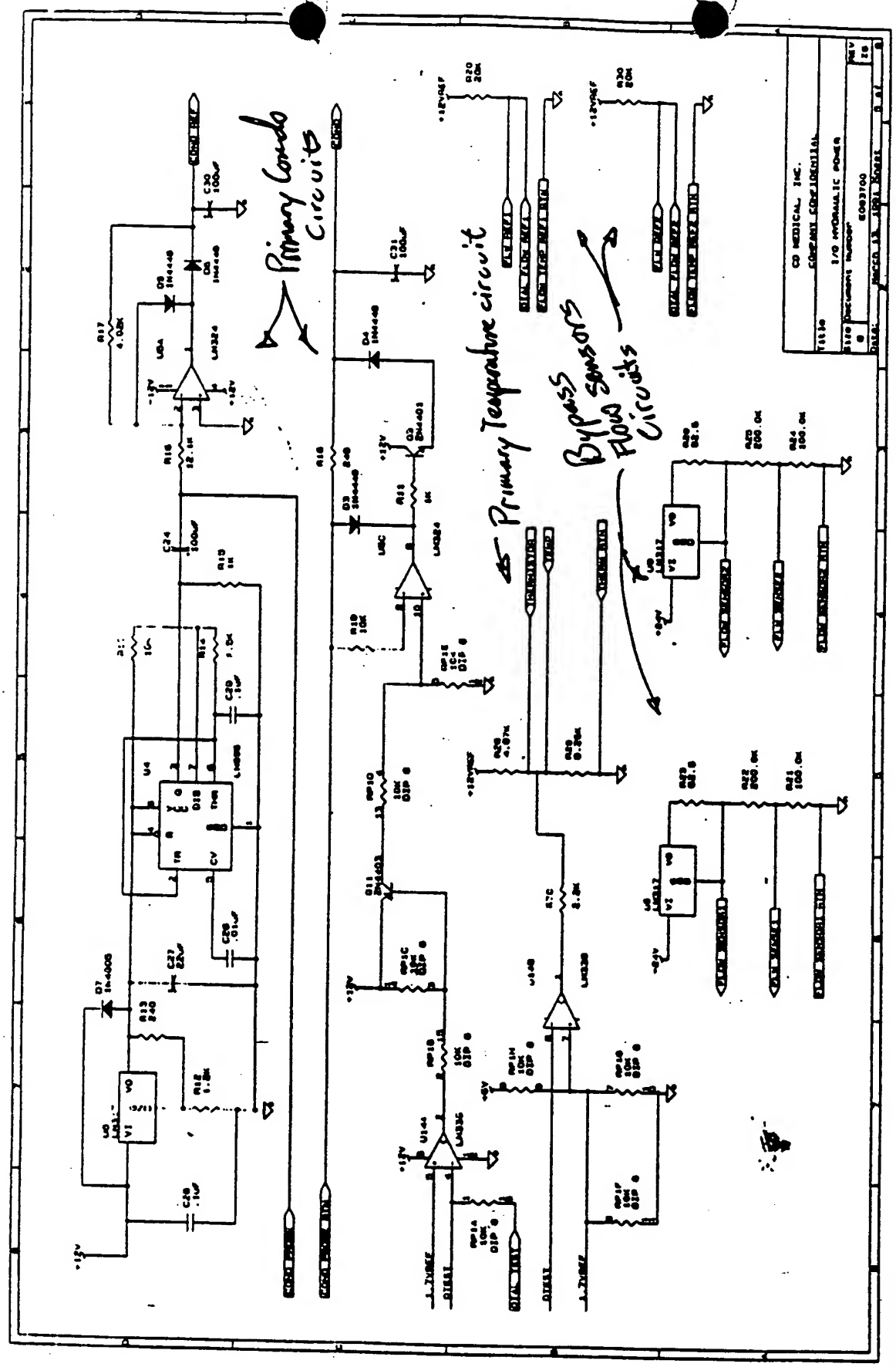
   e. flow sensors
      Bypass 1 and 2 Flow Sensors
      - IO Hydraulic Power Board Page 5 of 8 REVZ6
      End of Stroke Sensors
      - UF Power Board Page 8 of 9 REVZ9

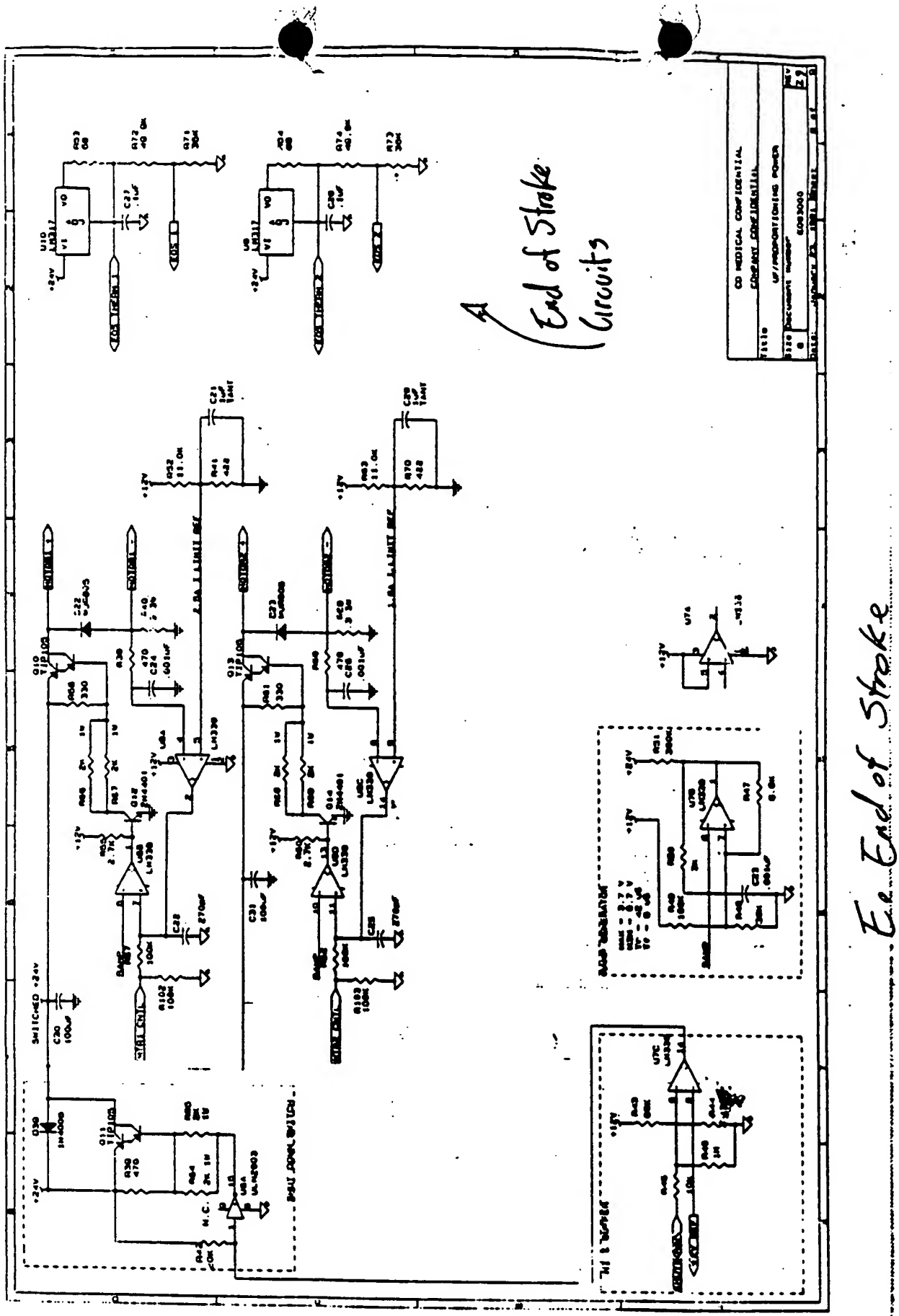

A. Blood Leak Circuit (Top Left)



b. Interlock Circuits


C.O. Air Detector Circuit


Primary Condo Circuits
Primary Temperature circuit
Bypass sensors Flow circuits
D. Primary Temp & Condo


End of Stroke Circuits
End of Stroke